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February 24, 2005

Lester Crawford, D.V.M., Ph.D.
Commissioner of FDA
Food and Drug Administration
5600 Fisher Lane, Room 1471
Rockville, MD 20587

Re: Docket No. 2005-P-0072
Citizen Petition related to SJS and TEN warnings on Ibuprofen products

Dear Doctor Crawford:

Last week's extraordinary FDA hearing on pain relieving drugs clearly demonstrated that the public and medical community wants the FDA to provide more information on the potential side effects that can result from both prescription and non-prescription drugs.

Just before last week's hearing, three other scientists and I formally filed a citizen petition with the FDA asking that the agency immediately require warning labels and instructions about Steven Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) be placed on all prescription and over-the counter ibuprofen products sold in the U.S. Joining us as signators were parents whose children experienced fatal or severe reactions from the normal use of pediatric ibuprofen products.

We are also asking the FDA to begin an immediate investigation as to whether McNeil Pharmaceuticals or Wyeth Consumer Healthcare, manufacturers of Children's Motrin and Children's Advil ibuprofen products willingly withheld information from the agency and the public regarding these side effects associated with the use of ibuprofen.

Following last week's special hearing, your agency indicated it would act on the joint committee's recommendations in a timely manner. We are asking you to do the same on our petition. Each day that goes by without a warning label on ibuprofen products regarding SJS and TEN is another day that the public's health will remain at risk with great human and financial consequences.

Evidence in support of the causal relationship between ibuprofen and SJS and TEN in the scientific literature is strong. It is well-documented and recognized by the leaders in the scientific community. One such study was done by the SCAR study group, which consisted of respected dermatologists and epidemiologists who conducted an international case-control study that clearly implicates and demonstrates a statistically significant causal relationship between ibuprofen and SJS and TEN with a RR of 5.3, 95% (CI 1.2-25.) Other case reports confirm that both adults and children are at risk from

SJS/TEN associated with the use of ibuprofen. Of course, the mortality rate associated with toxic epidermal necrolysis can be as high as 30%, if the early symptoms are not recognized, and the diagnosis of SJS and TEN are delayed.

The FDA need look no further than the Aspirin and Reye Syndrome experience as an example of how a low frequency use of a discretionary drug product can result in significant impacts to the health of the American public. When the association between Reye Syndrome and Aspirin was confirmed, it made the benefit risk unacceptable and the FDA mandated warnings on aspirin products regarding Reye Syndrome. That situation is almost exactly like that between ibuprofen and SJS/TEN.

Today, there is a greater risk of developing SJS/TEN and a higher mortality rate associated with ibuprofen than there is between aspirin and Reye Syndrome. Yet while the FDA requires manufacturers of aspirin products to place warnings about Reye Syndrome on product labels, the FDA does not require such warnings about SJS and TEN on ibuprofen products.

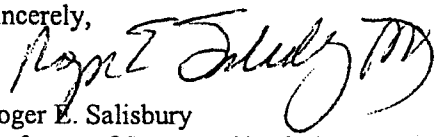
Some Ibuprofen products in Europe are required to have SJS/TEN warnings on their product labels. Canadian Health authorities in all likelihood will also shortly mandate SJS/TEN warnings be placed on prescription ibuprofen products sold in their country as part of their class labeling initiatives for NSAIDs. It is time that there be similar warnings required in the United States

We are asking the FDA recognize the growing scientific evidence that potentially fatal side effects can occur from the normal use of ibuprofen and that the agency take action to put adequate information and warning about possible SJS/TEN side effects on all prescription and over the counter ibuprofen products.

The hearings last week showed the importance of providing adequate warning and information to consumers on the risks associated with NSAIDs. By taking quick action on the recommendations of that committee, the FDA can take a first step toward regaining the trust of the public. By acting on this petition in a timely manner and ordering that ibuprofen products contain a warning about SJS and TEN, the FDA will be taking another step in helping protect the public health of our nation.

Thank you for your prompt attention and consideration of this matter.

Sincerely,



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cc: Mike Leavitt, Secretary of Health and Human Services
Steven K. Galson, M.D., M.P.H., Acting Deputy Center Director, CDER
Claude A. Allen, Deputy Secretary of Health and Human Services
U.S. Senator Christopher Dodd
U.S. Senator Charles Grassley

ENCLOSURES
WERE NOT SCANNED

ENCLOSURE TYPE: Additional Papers
20050228 14:51:1106 Roger E. Salisbury

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